Supreme Court, U.S.
FILED

05-100 MAY 18 2005

OFFICE OF THE CLERK

No. ____

In The
Supreme Court of the United States

DR. GEORGE PIECZENIK
Petitioner,
v.
DOMANTIS,JON DUDAS, LESTER M. CRAWFORD, CAMBRIDGE ANTIBODY TECHNOLOGY GROUP, and MRC-LABORATORY OF MOLECULAR BIOLOGY
Respondents

On Petition For Writ of Certiorari To The Appeals Court Of the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

Dr. George Pieczenik, *Pro Se*
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Questions Presented for Review

1) Whether Dr. Pieczenik, *pro se*, was denied his Constitutional right, under Clause 8, section 8 when the Court of Appeals for the Federal Circuit District ignored the affidavits of three Nobel laureates for defining combinatorial library sizes and deferred to the scientifically primitive, defective and adversarial *stare decisis* Markman hearing process to determine claim construction?

2) Whether Dr. Pieczenik, *pro se*, was denied his Fourteenth Amendment right to Due Process when the scientifically primitive Boston District Court did not take into account the motion for re-consideration based on surprisingly discovered evidence of infringement identified in the honest Southern District of New York?

3) Is *stare decisis* is a proper legal historical constraint for the Doctrine of Patent Exhaustion, in light that recombinant combinatorial libraries are re-made in their use?

4) Are all *pro se* Writ of Certiorari to this Court denied *a priori*?

5) Does the Buck v Bell sterilization of "three generations of imbeciles" still stand? Does specious science still rule supreme with this Court?

6) Does the medieval and monstrous assumption, that the King can do no wrong, still stand?

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Authorities, Citations, and Patents Cited

CF. Teleflex, Inc. v. Ficosa N. Am. Corp. 299 F.3rd 1313, 1329 (Fed.Cir. 2002)

Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l Inc., 246 F.3d 1336, 1348, 57 USPQ2d 1953, 1959 (Fed. Cir. 2001) p. 10

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722

General Electric Co. v. Brenner, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). p.17

General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364

*Hoffman La Roche, Inc. vs Promega Corp.*323 F.3rd 1354(Fed.Cir 2003)p.20

Lampi Corp. v. American Power Products Inc., 228 F.3d 1365, 1376, 56 USPQ2d 1445, 1453 (Fed. Cir. 2000) p.9

Markman v. Westview Instruments, Inc., 517 U.S. 370, 390 (1996)

Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997). p.10

THE PIECZENIK PATENTS

U.S.Patents 6,605,448; 5, 866, 363; 4, 359, 535 and 4, 528, 266

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES SUPREME COURT

I, Dr. George Pieczenik, *pro se*, respectfully request that the Honorable Justices of the Supreme Court grant a Writ of Certiorari to review the judgment of the Court of Appeals for the Federal Circuit rendered on January 13, 2005 and the denial of the Petition for Re-Hearing and the Petition of Re-Hearing En Banc on February 17th, 2005 (04-1477)

OPINIONS BELOW

The opinion of the Court of Appeal for the Federal Circuit is the subject of this Petition is *Pieczenik v Domantis 04-1447* and is set forth as Appendix A and the opinion of Judge Shira Scheindlin *1:03 CV 06336(SAS)* as is set forth as in Appendix B.

STATEMENT OF THE BASIS FOR JURISDICTION

I, Dr. George Pieczenik, *pro se*, believe I may petition the Court under Title 28 of the United States Code § 1254 and §1257(a) 2002 to review the ruling of the Court of Appeals for the Federal Circuit and the denial of the Petition for a Re Hearing and a Petition for a Re-Hearing En Banc as decided February 17th, 2005.

Background: The Court of Appeals for the Federal Circuit Fails to Understand the Need for A Queens Bench Representative to Our Provincial Patent Courts.

What has this puny patent case and the failure of the adversarial Markman hearing to do with such grave matters of our rights and liberties?

Only this, once through scientific indifference or judicial intellectual laziness one act of injustice and by degrees the poison of indifference by being convenient may cripple and destroy those rights and liberties.

It matters not whether the Pieczenik case is about a pro se inventor or the largest pharmaceutical house in the world.

What matter not, if the sum of the infringer's license is 1 dollar, or 1 penny, or the fiftieth part of the smallest fraction of one penny,

It matters not one single jot.

For the case of Pieczenik v. Domantis is none of these things. It is not Dr.Pieczenik's prevailing or Dr. Pieczenik's not prevailing that concerns us now. It is something greater by far.

It is Dr. Pieczenik's right to heard as a *pro se* inventor of America; to be heard in defense of his patent and ideas, so wantonly pitched into the mire.

Because of this monstrous assumption....this medieval and monstrous assumption ..that the King Can Do No Wrong.

And to maintain the common rights of any *pro se* American inventor against the King

I, Dr. Pieczenik, will fight to the last breath of my body and to last drop of my blood

And I believe with all my heart that this Court will accept my view

There is only one course left open to this Court.

Namely this, let this Court not rest until this Court has remanded Dr. Pieczenik's petition to the Court of Appeals for the Federal Circuit to consider the Affidavits of Nobel Laureates.

This Court shall articulate, the time honored phrase, a phrase that has always stirred in people and I hope always will stir. Wherever you may be in Nobel laboratories in Cambridge, England ; in humble state Universities laboratories; or in the humblest little lab in the corner of the humblest little cubicle- **"LET RIGHT BE DONE".**

Unfortunately, it seems that the Court of Appeals for the Federal Circuit has ignored the Affidavit of Lord Sydney Brenner. This is ignoring the Queens Bench rulings on all patent cases in the British Empire. For Lord Brenner is more than a simple Nobel Laureate. He is Order of the Garter, he is knighted by the Queen and more importantly he is the scientist the Queens Bench calls to decide all molecular biology patents. His word is law in the British Empire on issues of Patent claim construction.

Here, the Court of Appeals for the Federal Circuit didn't even know who he was or is. He created all of phage molecular biology, he created the concept and the term of the codon; he created the concept and the term of messenger RNA; he defined the whole neuronal network of a living organism; he defined the whole gĕnomic complement of a living organism; he defined the genetics of death and differentiation, he trained thousands of scientists around the world, he heads up research institutes in Singapore, Cambridge England and the Salk. He is the Queens Bench definition of claim terms in all patents in the whole of the British Empire.

He is *stare decisis* to all Modern Common Law in molecular biology.

Plaintiff brought Sydney Brenner into this case to save the reputation of the Court of Appeals for the Federal Circuit before it makes a more complete laughing stock of itself in the scientific community in supporting a completely idiotic claim construction by the provincial Boston Court. This claim construction was based on specious and fraudulent science presented to this provincial Court with intent to deceive this Court. The stubbornness, stupidity, denial and prejudices of the Boston Court would not allow itself to even consider true science and even honest evidence from the honest Court of Judge Shira Scheindlin's Court, .

What is at stake here is not this patent case, or this patent but the credibility of this Court and all the District Courts to the scientific establishment and to scientific history.

There will be a time when rational thought will replace religious superstition in this Country and at the time Francis Crick will be consider much as Jesus is considered presently. And Sydney Brenner will be considered much like Saul of Tarsis a.k.a. Paul.

That is why for this Court to disregard Lord Brenner's affidavit will be like the pope disregarding an epistle from Paul. Or, like President Roosevelt disregarding Einstein's letter on the making of an atom bomb.

Has this Supreme Court ever made any mistake in accepting specious science?

The best Supreme Court which ever existed was probably the Supreme Court that created a ruling and stare decisis for the worst human liquidation in the history of humanity.

This Court had Oliver Wendell Holmes, Louis Brandeis, and ex-President Taft, among others. One can not think of a more profound U.S. Supreme Court.

And, yet, like this case, it was suckered by a collusive defense and specious scientific evidence on the genetics of intelligence.

The two page decision in the Buck v Bell case is a stain on this Court with the blood of all those liquidated in the name of negative eugenics. It is a case which legitimized the sterilization of thousands of Americans. But, also legitimized the laws involved in negative eugenics which were taken verbatim to germany for the liquidation of millions and millions and millions and millions and millions and millions. This is blood on the hands of this Supreme Court that cannot be washed away.

This Court has not even accepted the responsibility of this horrible historical crime in which it was the prime mover.

There can be no truth and reconciliation between scientists and this Court unless this Court admits it used specious science to legitimize horrible and inhumane laws.

That is why this Court must overthrow all processes of determining scientific fact that is based on an adversarial system. It is clear that an adversarial structure to determine scientific truth is complete nonsense. One experiment can disprove thousands in debates. Einstein did not care that the whole german establishment called his physics "Jewish Physics".

Would the Court of Appeals for the Federal Circuit have disregarded an affidavit from Einstein?

More than fifty percent of all Markman rulings are overturned. That means they are completely random. For, there are only two possibilities in rulings from a Court of law. And that is the problem with the process.

The District Court and the Court of Appeals should have implemented Rule 706. This allows these Courts to bring in their own "expert witnesses". Instead, these Court's use law clerks who have failed molecular biology courses and, therefore, did not become physicians, but now are lawyers by default. This has lead to very snide *ad hominem* rulings in molecular biology rulings with exceptionally stupid logic that are over the heads of the supervising Judge.

Instead, our provincial Courts should follow the British Queens Bench and bring in expert scientist as they do with bringing in Lord Sydney Brenner.

I offered Lord Brenner's testimony to the Court of Appeals, as my courtesy to this Court, and, also, two other very important Nobel laureates. Rich Roberts, whose company New England Biolabs took a modest license on Plaintiff's patent and had previously sold an infringing combinatorial library to Defendant. And Bruce Merrifield created solid state peptide and nucleic acid chemistry which is the basis for all pharmaceutical combinatorial synthesis.

In addition, as Crick is like Jesus, and Brenner is like Paul, it was Crick's dying wish, as if Christ on the Cross, that Brenner give Plaintiff his support, in Plaintiff's attempt to try and correct the legal disaster these Court's have now created in combinatorial library molecular biology patents.

And, yet, these Court's have disregarded the call of history.

I have not bothered to cite any case outside of the Buck v. Bell case. For the problem is not with the lower Court, nor the CAFC, but with this Court's own bloodied hands.

And its lack of understanding that it is own confused internal logic that allowed itself to be suckered with specious science in order to preserve a reflection of a British system of law that is much more adaptable than its apprentice colonial Courts.

If the Queens Bench has Lord Brenner sitting, then perhaps it is time the Supreme Court, allow itself under rule 706 for Lord Sydney Brenner to create a molecular biology panel.

The legitimacy of this Court is at stake among the scientific community and, at least, 15 Nobel laureates, believe that this Court or any District Court should not be in the business of defining molecular biology claims. The lawyers and the Courts are looked upon as default pre-med failures proud of their ignorance of science and contemptuous of learning.

This is clear a recipe for disaster. The public now only believes in DNA evidence, not in the adversarial system of uncovering "truths". Every law and order program on TV has some mention of DNA evidence. Without that DNA mention the public does not believe the evidence. All the legal sites and *stare decisis* references are completely disregarded and considered irrelevant verbiage.

To disregard the fathers of DNA so casually will mark this Court and the CAFC as probably the most ignorant Court since the Buck v. Bell Court. And, yet, that was the best Supreme Court which ever sat.

To disregard The Petition of Right so casually will mark this Court and the CAFC as probably the most conservative Court since the Dred Scott decision.

The adversarial *stare decisis* legal system is falling apart and

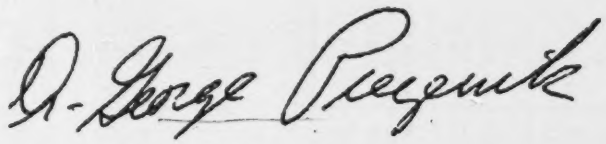
requires a rapid infusion of Rule 706 advisory panels in its evolution to a more inquisitorial system.

CONCLUSION AND PRAYER

I move, in this petition, that the Supreme Court of the United States properly address the issue of the Markman hearing as provincial, defunct and a specious adversarial method of determining claim construction. I move that this Court institute Rule 706 and appoint a panel of scientific advisors to determine claim construction in molecular biology patents.

I move this Court instruct the lower Courts to "Let Right Be Done".

I further declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct. Signed this day of 18th of May, 2005 at New York City, New York.



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APPENDIX A

NOTE: Pursuant to Fed. Cir. R. 47.6, this disposition is not citable as precedent. It is a public record.

United States Court of Appeals for the Federal Circuit

04-1477

GEORGE PIECZENIK,

Plaintiff-Appellant,

v.

DOMANTIS,

Defendant,

and

JON DUDAS, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE,

Defendant-Appellee,

and

LESTER M. CRAWFORD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION,

Defendant-Appellee, And

CAMBRIDGE ANTIBODY TECHNOLOGY GROUP,

Defendant,

and

MEDICAL RESEARCH COUNCIL-LABORATORY OF MOLECULAR BIOLOGY,

Defendant.

DECIDED: January 13, 2005

Before RADER, BRYSON, and GAJARSA,

Circuit Judges.

PER CURIAM.

DECISION

Dr. George Pieczenick appeals the decision of the United States District Court for the Southern District of New York dismissing his claims against the United States Patent and Trademark Office ("PTO") and the Food and Drug Administration ("FDA") in case No. 1:03-CV-06336. We affirm.

BACKGROUND

Dr. Pieczenick is the inventor of U.S. Patent Nos. 6,605,448 ("the '448 patent") and 5,866,363 ("the '363 patent"). He is also the named inventor on a separate published patent application. Appearing pro se, Dr. Pieczenick instituted this litigation, claiming that several of the defendants infringed the '448 and '363 patents. Concurrent with his infringement claim, Dr. Pieczenick also brought suit against the Director of the PTO and the Commissioner of the FDA. Dr. Pieczenick averred in his complaint that the PTO was dilatory in issuing the '448 and '363 patents, waiting for more than 12 years to

issue either patent. To mitigate the harm from that delay, Dr. Pieczenick asked the district court to grant a writ of mandamus directing the PTO to reexamine all patents related to the '448 and '363 patents that issued after he filed his original patent applications. Such an undertaking, according to Dr. Pieczenick, would require the reexamination of more than 1,000 separate patents. Dr. Pieczenick also asked the district court to grant a writ of mandamus directing the FDA to reexamine the biologic license for the drug Erbitux in light of Dr. Pieczenick's published patent application. Finally, Dr. Pieczenick alleged that the PTO and FDA had engaged in numerous unlawful conspiracies that violated the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 et seq., and he asked for appropriate relief from those alleged violations. The PTO and FDA subsequently moved to dismiss the action for lack of subject matter jurisdiction. While Dr. Pieczenick's complaint individually named the Commissioner of the FDA and the Director of the PTO, the district court held that those officials were sued in their official capacity, not their personal capacity. The district court next determined that the FDA and PTO did not owe Dr. Pieczenick a duty to reexamine the patents and drug license in question, and the court therefore declined to issue a writ of mandamus. Finally, the district court ruled that the PTO and

FDA were not "persons" within the meaning of the RICO statute, and that the court therefore lacked subject matter jurisdiction with respect to the RICO claims. Dr. Pieczenick appeals from those rulings.

DISCUSSION

As a preliminary matter, the district court was correct to conclude that this suit was brought against the heads of the PTO and FDA in their official capacity, not in their personal capacity. Throughout Dr. Pieczenick's complaint and his pleadings, it is clear that he is complaining of the actions of the agencies as a whole, rather than the conduct of any specific officials. For instance, he refers to the alleged conspiracies as being committed by the "PTO" or "FDA." Furthermore, the relief he requests is predicated upon the authority of the Director and Commissioner as heads of those agencies. Therefore, Dr. Pieczenick's suit is essentially against the PTO and FDA. Robinson v. Overseas Military Sales Corp., 21 F.3d 502, 510 (2d Cir. 1994). Dr. Pieczenick argues that even if his suit is actually against the PTO or FDA, rather than the agencies' heads in their personal capacity, the United States is still not a party to the suit, and sovereign immunity does not attach. On appeal, Dr. Pieczenick relies on the Supreme Court's statement in O'Melveny & Myers v. Federal Deposit Insurance Corp., 512

U.S. 79, 85 (1994), that "the FDIC is not the United States" to buttress that argument. He then attempts to liken the PTO and FDA to the FDIC. However, whether an entity, such as the FDIC, should be treated as the United States is a question of context, and is based on the legislation creating the agency. Auction Co. of Am. v. Fed. Deposit Ins. Corp., 132 F.3d 746, 748 (D.C. Cir. 1997). Moreover, unlike the FDIC, which is independent of any executive branch department, the FDA is an entity within the Department of Health and Human Services, 21 U.S.C. § 393(a), and the PTO is agency within the Department of Commerce, 15 U.S.C. § 1. Dr. Pieczenick offers no reason to conclude that, despite the status of the FDA and the PTO as executive branch agencies, his suit against those agencies should not be regarded as a suit against the United States. Therefore, we agree with the district court's decision and hold that Dr. Pieczenick's suit is subject to the restrictions of sovereign immunity and can proceed only to the extent that Congress has waived sovereign immunity. Although the Administrative Procedure Act waives sovereign immunity for mandamus actions against federal agencies, 5 U.S.C. § 702, we have stated that mandamus is available as a remedy for a plaintiff "only if he has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty." Franchi

v. Manbeck, 972 F.2d 1283, 1289 (Fed. Cir. 1992). In this case, the district court determined that the Director of the PTO did not owe Dr. Pieczenick a nondiscretionary duty to reexamine all issued patents that relate to the '448 and '363 patents. We agree with the district court that, while the PTO may sua sponte decide to reexamine an issued patent, such a reexamination rests solely in the PTO's discretion.

See 35 U.S.C. § 303(a) ("On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him."). Therefore, the PTO does not owe Dr. Pieczenick a clear duty, and mandamus is inappropriate. Additionally, Dr. Pieczenick did not exhaust all other avenues of relief, because he failed to make a formal request for reexamination of the patents. 35 U.S.C. §§ 302, 311. Dr. Pieczenick argues that such a remedy is unavailable to him because of the prohibitive costs of requesting a reexamination of more than 1,000 patents. Yet Dr. Pieczenick did not make even a single proper request for reexamination by the PTO and thus did not make any attempt to comply with the administrative procedures available to him. We agree with the district court that under these circumstances the Director of the PTO has no legal duty to reexamine a large number of patents sua sponte.

The district court also determined that the Commissioner of the FDA did not owe Dr. Piezcenick a duty to reexamine the biologic license application for Erbitux in light of Dr. Piezcenick's patents. Biologic licenses are required by the FDA to ensure that a biological product meets prescribed standards of safety, purity, and potency. 21 C.F.R.§ 601.2(a). Dr. Pieczenick has not pointed to any statute or regulation authorizing or requiring the FDA to reexamine a biologic license in light of newly issued or published patents. Furthermore, imposing such a requirement on the FDA would not be consistent with the purpose underlying the requirement for biologic licenses; namely, to guarantee the safety, purity, and potency of the drug. Because Dr. Pieczenick has not shown that the FDA has a clear duty to reexamine biologic licenses in light of new patents, it would not be appropriate for the district court to issue a writ of mandamus.

Finally, the district court dismissed the RICO claims for lack of subject matter jurisdiction. As we have stated, Dr. Pieczenick's complaint was essentially against the United States. However, it is well settled that the government cannot be liable under RICO because the United States does not fall within the statute's definition of a "person" capable of violating RICO. United States v. Bonanno Organized Crime

Family, 879 F.2d 20, 21-27 (2d Cir. 1989). Additionally, the existence of "racketeering activity" is a prerequisite to bringing a civil RICO action. Such activity must be "indictable" under state and federal criminal laws. Since federal agencies are not subject to state or federal criminal prosecution, RICO claims cannot be brought against them. Berger v. Pierce, 933 F.2d 393, 397 (6th Cir. 1991). We therefore agree that the district court was correct to dismiss the RICO claims for lack of subject matter jurisdiction.

APPENDIX B

GEORGE PIECZENIK, Plaintiff,-against-CAMBRIDGE ANTIBODY TECHNOLOGY GROUP, DOMANTIS, MEDICAL RESEARCH COUNCIL-LABORATORY OF MOLECULAR BIOLOGY, THE COMMISSIONER OF PATENTS AND TRADEMARKS OF THE UNITED STATES PATENT OFFICE, AN AGENCY OF THE DEPARTMENT OF COMMERCE, and THE COMMISSIONER OF FOOD AND DRUGS, Defendants. 03 Civ. 6336 (SAS)

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

2004 U.S. Dist. LEXIS 11049 June 16, 2004, Decided June 16, 2004, Filed

PRIOR HISTORY: Pieczenik v. Cambridge Antibody Tech. Group, 2004 U.S. Dist. LEXIS 9185 (S.D.N.Y., May 14,2004)

DISPOSITION: [*1] Plaintiffs motion for petition of right denied. COUNSEL: George Pieczenik, Plaintiff, Pro se, New York, New York.

For Defendants: Lara K. Eshkenazi, Assistant United Stales Attorney, New York, New York.

JUDGES: SHIRA A. SCHEINDLIN, U.S.D.J. OPINIONBY: SHIRA A. SCHEINDLIN OPINION: MEMORANDUM OPINION AND ORDER SHIRA A. SCHEINDLIN, U.S.D.J.:

In a lawsuit that was dismissed for lack of subject matter jurisdiction on sovereign immunity grounds, pro se plaintiff George Pieczenik sued the Commissioners of the United States Patent and Trademark Office and the Food and Drug Administration. See Pieczenik v. Cambridge Antibody Tech. Group, 2004 U.S. Dist. LEXIS 9185, No. 03 Civ. 6336, 2004 WL 1118500 (S.D.N.Y. May 14, 2004) (the "May 14 decision") Pieczenik now moves for a "petition of right," "a proceeding in chancery by which a subject claims that a debt is owed by the Crown or that the Crown has broken a contract or wrongfully detained the subject's property." Black's Law Dictionary (8th ed. 2004). However, "the English remedies of petition of right, monstrans de droit, and traverse of office, were never introduced into this country as part of our common law." United States v. Lee, 106 U.S. 196, 238-39,27 L. Ed, 171,1 S. Ct. 240 (1882) [*2] (Gray,!, dissenting); see also Ruggiero v. Compania Peruana de Vapores "Inca Capac Yupanqui", 639 F.2d 872, 880 n.10 (2d Cir. 1981) (Friendly, J.) (same).

Nonetheless, the doctrine of sovereign immunity emerged directly from the petition of right, see generally Lee, 106 U.S. at

205-06 (discussing petition of right and its link to Congress' limited authorization of suit against United States); see also John J. Gibbons, The Eleventh Amendment and State Sovereign Immunity: A Reinterpretation, 83 Colum. L. Rev. 1889 (1983) (tracing the history of state sovereign immunity to the petition of right), which - as is the case with sovereign immunity - required the crown's consent to be sued. See Chisholm v. Georgia, 2 U.S. (2 Dall.) 419, 444, 1 L. Ed. 440, 2 Dall. 419 (1793) (Iredell, J., dissenting) ("In all cases of petition of right, of whatever nature is the demand, I think it is clear beyond all doubt, that there must be some indorsement or order of the King himself to warrant any further proceedings. The remedy, in the language of Blackstone, being a matter of grace, and not on compulsion."). Pieczenik's request for a petition [*3] of right therefore raises the same concerns, and requires the same resolution, as the May 14 decision. Because the United States has not waived its sovereign immunity, Pieezenik's motion for a petition of right is DENIED.

Accordingly, the Clerk of the Court is direct to close this motion [number 96 on the docket sheet], and Pieczenik is reminded that this case is closed. See Pieczenik, 2004 U.S. Dist. LEXIS 9185, 2004 WL 1118500, at +7. SO ORDERED: Shira A. Scheindlin U.S.D.J. Dated: June 16, 2004

APPENDIX C

GEORGE PIECZENIK, Plaintiff-Appellant, v. DOMANTIS, Defendant and, JON DUDAS, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE, Defendant-Appellee, and, LESTER M. CRAWFORD, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, Defendant-Appellee, and CAMBRIDGE ANTIBODY TECHNOLOGY GROUP, Defendant, and MEDICAL RESEARCH COUNCIL-LABORATORY OF MOLECULAR BIOLOGY, Defendant. 04-1477 UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT 125 Fed. Appx. 283; 2005 U.S. App. LEXIS 4412 February 17, 2005, Decided February 17, 2005, Filed NOTICE: [**1] THIS DECISION WAS ISSUED AS UNPUBLISHED OR NONPRECEDENTIAL AND MAY NOT BE CITED AS PRECEDENT. PLEASE REFER TO THE RULES OF THE FEDERAL CIRCUIT COURT OF APPEALS FOR RULES GOVERNING CITATION TO UNPUBLISHED OR NONPRECEDENTIAL OPINIONS OR ORDERS.

PRIOR HISTORY: Pieczenik v. Domantis, 120 Fed. Appx. 317, 2005 U.S. App. LEXIS 571 (2005) OPINION: [*284] ORDER A petition for rehearing en banc having been filed

by the APPELLANT, and the matter having first been referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.The mandate of the court will issue on March 7, 2005.

APPENDIX D

GEORGE PIECZENIK, Plaintiff, -against- CAMBRIDGE ANTIBODY TECHNOLOGY GROUP, DOMANTIS, MEDICAL RESEARCH COUNCIL-LABORATORY OF MOLECULAR BIOLOGY, THE COMMISSIONER OF PATENTS AND TRADEMARKS OF THE UNITED STATES PATENT OFFICE, AN AGENCY OF THE DEPARTMENT OF COMMERCE, and THE COMMISSIONER OF FOOD AND DRUGS, Defendants.03 Civ. 6336 (SAS) UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK 2004 U.S. Dist. LEXIS 9185 May 14, 2004, Decided May 19, 2004, Filed

SUBSEQUENT HISTORY: Motion denied by Pieczenik v. Cambridge Antibody Tech. Group, 2004 U.S. Dist. LEXIS 11049 (S.D.N.Y., June 16, 2004) PRIOR HISTORY: Pieczenik v. Cambridge Antibody Tech. Group, 2004 U.S. Dist. LEXIS 4127 (S.D.N.Y., Mar. 16, 2004) DISPOSITION: Defendants' motion to dismiss for lack of subject-matter jurisdiction granted. Action closed. COUNSEL: [*1] George Pieczenik, Plaintiff, Pro se, New York, New York. For Defendants: Lara K. Eshkenazi, Assistant United States Attorney, New York, New York.

JUDGES: Shira A. Scheindlin, U.S.D.J. OPINIONBY: SHIRA A. SCHEINDLIN OPINION: OPINION AND ORDER SHIRA A. SCHEINDLIN, U.S.D.J.:

Dr. George Pieczenik, appearing pro se, brings this lawsuit against, inter alia, the Commissioners of the United States Patent and Trademark Office ("PTO") and the Food and Drug Administration ("FDA") (collectively "defendants"). Pieczenik seeks relief pursuant to the Mandamus and Venue Act n1 and Racketeer Influenced and Corrupt Organizations Act ("RICO"). n2 Defendants move to dismiss the action against them for lack of subject-matter jurisdiction. n3 Pieczenik cross-moves for: (1) dismissal of defendants' motion n4 and (2) a writ of mandamus requiring the U.S. Government to file a "Motion of Substitution" and a new "Amended Reply explaining the [National Institutes of Health ("NIH")], the Army and the Navy's infringement [of Pieczenik's patents]." n5 For the following reasons, defendants' motion to dismiss for lack of subject-matter jurisdiction is granted and Pieczenik's cross-motions are denied.

- - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -n1 28 U.S.C. § 1361. Pieczenik does not identify the statutory basis for his request to compel defendants to reexamine certain patents. However, because this relief is only available pursuant to this Court's mandamus jurisdiction, I will assume that the non-RICO claims are premised on section 1361. [*2] n2 18 U.S.C. § 1961 et seq. n3 See Fed. R. Civ. P. 12(b)(1). n4 Pieczenik seeks to strike defendants' motion for their failure to substitute the United States as the defendant by filing either a "Motion of Substitution" or "Declaration of Representative." Plaintiff's Reply Memorandum of Law in Further Opposition to Defendants' Motion to Dismiss ("Pl. Sur-Reply") at 2.n5 Id. - - - - - - - - - - - - End Footnotes- - - - - - - - - - -

I. FACTS A. Background At the heart of this case are patent rights held by Pieczenik and allegedly infringed by various parties. Specifically, Pieczenik owns U.S. Patent Nos. 6,605,448 ("'448 Patent") and 5,866,363 ("'363 Patent"), both entitled "Method and Means for Sorting and Identifying Biological Information." n6 Pieczenik alleges that these patents were filed on August 28, 1985 and issued by the PTO

on August 12, 2003 and February 2, 1999, respectively. n7 Additionally, Pieczenik filed a third patent application with the PTO, which was published on October 30, 2003 and addresses the "treatment of refractory [*3] human tumors with epidermal growth factor receptor and HER1 mitogenic ligand (EGFRML) antagonists." n8 Pieczenik alleges that the PTO failed to issue the '448 and '363 patents in a timely manner, waiting for approximately eighteen years from the original filing date to issue the '448 patent and about twelve years to issue the '363 Patent. n9 - - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - - -n6 Third Amended Complaint ("Compl.") PP 23-24. n7 Id. PP 13-14. The filing dates listed in the PTO database are: November 18, 1998 for the '448 Patent and February 28, 1991 for the '363 Patent. See www.uspto.gov. n8 Id. P 15 (citing U.S. Patent Application No. 2003/0202973). n9 Id. P 43.- - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - -

B. Allegations Relating to Mandamus Relief 1. The Commissioner of the PTO Pieczenik avers that despite his request that the Commissioner of the PTO, "Biotechnology Section heads[,] and examiners [] reexamine all patents

within the scope of the section 102(e) snap back of the '363 and '448 patents," n10 they took no action. In particular, [*4] Pieczenik cites an e-mail message that he sent to PTO officials Nicholas Godici, Bruce Stoner, George Elliott, and John Brusca in which he states: Could you please tell me if the [PTO] will order its own re exams of patents containing phage display combinatorial libraries that were filed after my ['448 Patent] was filed in 1985 but issued in 2003 with a 102e "snap back" to 1985. I understand that I can pay a fee to request re exams, but it is quite expensive and the [PTO] took 18 years to issue this patent which now because of GATT has only 2 years of term and therefore I believe the [PTO] should have a responsibility to address its delay in issuing this patent and allowing all the other patents in the meantime that I would have to address individually. This would be prohibitively expensive, for a pro se inventor such as myself n11

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another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language[.] 35 U.S.C. § 102(e). [*5] n11 Compl. P 40 (excerpting e-mail message).

- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -The projected scope of Pieczenik's request is significant - he asserts that the PTO has "issued over 1,000 patents, inter alia, in the 18 years while the '448 patent was secret," that should be reevaluated in light of his patent. n12 To that end, Pieczenik requests reexamination of all Cambridge Antibody Technology ("CAT") and Domantis, Inc. ("Domantis") patents relating to combinatorial libraries subsequent to the filing of the '448 patent. n13 Additionally, he seeks to compel the Commissioner of the PTO to review Bristol-Myers

Squibb Co.'s ("Bristol-Myers") U.S. Patent No. 5,565,325 in light of the issued '363 and '448 patents. n14 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - - N12 Id. P 43. n13 See id. PP 76-77. n14 Defendants respond with a sworn declaration indicating that Pieczenik has never formally applied for a reexamination of certain patents held by Bristol-Myers. See 1/30/04 Declaration of Gerald A. Dost, Senior Legal Advisor for the PTO P 4 (citing U.S. Patent Nos.: 5,565,325 (Oct. 15, 1996); 5,709,859 (Jan. 20, 1998); 5,840,302 (Nov. 24, 1998); 5,840,854 (Nov. 24, 1998); 5,876,718 (Mar. 2, 1999); 6,046,314 (Apr. 4, 2000); 6,132,722 (Oct. 17, 2000); 6,372, 215 (Apr. 16, 2002)). - - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - [*6]

2. The Commissioner of the FDA Pieczenik alleges that the FDA has "authority to maintain the Orange Book, [which lists] the unexpired and published patent applications relevant to the safety and efficacy and method of treatment of drugs." n15 "In addition, the FDA requires applications for Biologic License Application [("BLA")] and for New Drug Application ("NDA") a form 356h, which in line 13 states 'Patent information on any patent which claims the drug.'"

n16 Pieczenik avers that the approval of Erbitux required "filling out this form," n17 suggesting that the FDA has authority to reexamine patents listed or omitted for purposes of this application. - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - n15 Compl. P 10. n16 Id.; see also Dep't of Health and Human Servs. Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use ("FDA Form 356h"), Ex. N to Compl. n17 Compl. P 10. - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

C. Allegations Relating to RICO Conspiracies The PTO and the FDA are alleged to have engaged in numerous unlawful conspiracies. [*7] First, the FDA conspired with Bristol-Myers, and Merck AG ("Merck") to "manipulate the price of Genetic Systems and Imclone stock [to] take control of their respective monoclonal antibodies used for cancer treatment and remove the Jewish scientists and founders from their respective corporations." n18 Second, the FDA and the PTO colluded with the Department of Justice ("DOJ") to "ignore the fact that they are dealing and accepting filings and patents from a pharmaceutical company, Merck [], that has never been de-nazified and, therefore, is still a criminal enterprise

unto itself." n19 Third, the FDA and the PTO, along with Bristol-Myers, Merck, and unnamed defendants, have created: (1) "'free patent zones' as policy to allow foreign corporations and US pharmaceutical companies to 'walk over' individual American inventor patent rights in violation of the American Inventors Protection Act"; (2) "a non importation embargo of patent drugs from Canada in violation of [Pieczenik's] patent rights"; and (3) "a monopoly trust in violation of [Pieczenik's] patent rights." n20 Fourth, the PTO engaged in wire fraud through its communications with Medical Research Council-Laboratory [*8] of Molecular Biology, CAT, Dyax Corp., and Domantis. n21 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -n18 Id. P 59. n19 Id. P 60. n20 Id. PP 62-64. n21 Id. P 67. Pieczenik also suggests, in his motion papers, that "Plaintiff showed evidence of direct infringement by the FDA by its purchases of NEB libraries and . . . that other Government individuals and agencies directly infringed and induced to infringe the Pieczenik patents by their purchase of NEB combinatorial laboratories, i.e.[,] the NIH, the Army, the Navy, etc." Pl. SurReply at 2.

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II. APPLICABLE LAW A. Rule 12(b)(1) "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." n22 When the defendant challenges the legal sufficiency of the plaintiff's jurisdictional allegations, the court must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of the plaintiff. n23 However, "where evidence [*9] relevant to the jurisdictional question is before the court, 'the district court . . . may refer to [that] evidence.'" n24 Therefore, "in resolving the question of jurisdiction, the [] court can refer to evidence outside the pleadings and the plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." n25 The consideration of materials extrinsic to the pleadings does not convert the motion into one for summary judgment. n26 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - -

n22 Makarova v. United States, 201 F.3d 110, 113 (2d Cir.

2000). n23 See Robinson v. Government of Malaysia, 269 F.3d 133, 140 (2d Cir. 2001) (quotation marks and citation omitted).n24 Id. (alterations in original) (quoting Makarova, 201 F.3d at 113). n25 Luckett v. Bure, 290 F.3d 493, 496-97 (2d Cir. 2002). n26 See CCS Int'l Ltd. v. United States, 2003 U.S. Dist. LEXIS 23056, No. 03 Civ. 0507, 2003 WL 23021951, at *2 (Dec. 24, 2003).

---------- End Footnotes- ---------- [*10]

B. Principles of Sovereign Immunity "In any suit in which the United States is a defendant, there must be a cause of action, subject matter jurisdiction, and a waiver of sovereign immunity." n27 This is so because the United States ("United States" or "Government") is immune from suit except "as it consents to be sued." n28 Congress can waive the Government's sovereign immunity only through clear and unequivocal statutory language and may predicate such waiver on satisfaction of specific conditions. n29 This waiver "is a prerequisite to subject-matter jurisdiction but the issues of subject-matter jurisdiction and sovereign immunity are nonetheless 'wholly distinct.'" n30

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Presidential Gardens Assocs. v. United States, 175 F.3d 132, 139 (2d Cir. 1999). Section 1331, providing for federal question jurisdiction, is unrelated to a waiver of sovereign immunity. See, e.g., Doe v. Civiletti, 635 F.2d 88, 94 (2d. Cir. 1980) ("Section 1331 is in no way a general waiver of sovereign immunity. Such a waiver, if it exists at all, must be sought in the statute giving rise to the cause of action."). [*11] n28 United States v. Mitchell, 445 U.S. 535, 538, 63 L. Ed. 2d 607, 100 S. Ct. 1349 (1980) (quoting United States v. Sherwood, 312 U.S. 584, 586, 85 L. Ed. 1058, 61 S. Ct. 767 (1941)). n29 See CCS Int'l Ltd., 2003 U.S. Dist. LEXIS 23056, 2003 WL 23021951, at *2 (citing Lane v. Pena, 518 U.S. 187, 192, 135 L. Ed. 2d 486, 116 S. Ct. 2092 (1996) and United States v. Dalm, 494 U.S. 596, 608, 108 L. Ed. 2d 548, 110 S. Ct. 1361 (1990)). n30 Presidential Gardens Assocs., 175 F.3d at 139 (quoting Blatchford v. Native Village of Noatak, 501 U.S. 775, 786-87 n.4, 115 L. Ed. 2d 686, 111 S. Ct. 2578 (1991)).

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"An action against a federal agency or federal officers in their official capacities is essentially a suit against the United States." n31 Thus, a plaintiff pursuing a claim against a federal officer must demonstrate either that the suit is permissible under a "specific statutory authorization to sue the United States, or that in effect, the proceeding is not a suit against the United States." n32 For instance, courts have found that sovereign immunity does not shield the defendant [*12] officer who has acted: (1) in his "individual capacity, rather than on behalf of the United States, or outside the scope of his governmental authority"; (2) pursuant to his governmental authority, but in violation of the plaintiff's "clearly established constitutional or statutory rights"; or (3) pursuant to an unconstitutional grant of authority. n33

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n31 Robinson v. Overseas Military Sales Corp., 21 F.3d 502, 510 (2d Cir. 1994); see also 14 Charles Alan Wright, Arthur C. Miller & Edward H. Cooper, Federal Practice and Procedure § 3655, at 344 (3d ed. 1998) ("Suits against federal

agencies and officers may be barred by the doctrine of sovereign immunity if the conduct in question has been undertaken on behalf of the government."); Marshall v. National Ass'n of Letter Carriers Br. 36, 2003 U.S. Dist. LEXIS 1427, 2003 WL 223563, at *6 (S.D.N.Y. Feb. 3, 2003) ("Suits against federal agencies or federal officials in their official capacities are suits against the United States and are similarly barred absent an applicable waiver."). n32 14 Wright, Miller & Cooper, supra note 31, § 3655, at 344. [*13] n33 Id. at 376-79. Where a federal official is alleged to have personally violated a plaintiff's constitutional rights and no adequate remedial mechanisms are available to redress the injury, that plaintiff can assert a claim under Bivens v. Six Unknown Named Agents of the Fed. Bureau of Narcotics, 403 U.S. 388, 29 L. Ed. 2d 619, 91 S. Ct. 1999 (1971).

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C. Mandamus Relief Section 1361 provides: "The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed

to the plaintiff." n34 "Section 1361 'is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty.'" n35 Accordingly, mandamus is not granted lightly - it "is a drastic remedy available only in extraordinary situations." n36 A plaintiff seeking mandamus relief must demonstrate the following: "(1) [he] has a clear right to the relief sought, (2) [defendants have] a plainly defined and peremptory [*14] duty to perform the act in question, and (3) no other adequate remedy is available." n37

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n34 28 U.S.C. § 1361; see also Smith v. Lehman, 533 F. Supp. 1015, 1018 (E.D.N.Y. 1982) ("[Section 1361] does not confer jurisdiction but merely provides additional remedies where jurisdiction already exists."), aff'd, 689 F.2d 342 (2d Cir. 1982). n35 Franchi v. Manbeck, 972 F.2d 1283, 1289 (Fed. Cir. 1992) (quoting Heckler v. Ringer, 466 U.S. 602, 616, 80 L. Ed. 2d 622, 104 S. Ct. 2013 (1984)) n36 Morelli v. Alexander, 920 F. Supp. 556, 558 (S.D.N.Y. 1996). n37 Id. (emphasis added).- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - -Courts have held that section 1361 does not by itself

operate as a waiver of sovereign immunity. n38 However, "if a plaintiff seeks a writ of mandamus to force a public official to perform a duty imposed upon him in his official capacity[, under the so-called Larson-Dugan exception to sovereign immunity,] no separate [*15] waiver of sovereign immunity is needed." n39 The Supreme Court has explained: There may be, of course, suits for specific relief against officers of the sovereign which are not suits against the sovereign. . . . Where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions. The officer is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden. His actions are ultra vires his authority and therefore may be made the object of specific relief. n40 Thus, in order to fall within this exception to sovereign immunity, a plaintiff must demonstrate that the United States owed him a duty, which the defendant official failed to perform. - - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - -

n38 See, e.g., Washington Legal Found. v. U.S. Sentencing Comm'n, 319 U.S. App. D.C. 256, 89 F.3d 897, 901 (D.C.

Cir. 1996) ("It is well settled that this statute does not by itself waive sovereign immunity.") (citing cases); Lonsdale v. United States, 919 F.2d 1440, 1444 (10th Cir. 1990) ("Sovereign immunity is not waived by general jurisdictional statutes such as . . . 28 U.S.C. § 1361."); Coggeshall Dev. Corp. v. Diamond, 884 F.2d 1, 3 (1st Cir. 1989) ("The provisions of 28 U.S.C. § 1361 creating the federal mandamus action do not constitute a waiver of sovereign immunity by the United States."); Smith v. Grimm, 534 F.2d 1346, 1352 n.9 (9th Cir. 1976) ("We . . . note the bar of sovereign immunity as an additional impediment to plaintiff's allegation of mandamus jurisdiction. [Section 1361] is not a consent to suit by the sovereign.") (citation omitted). But see Drake v. Panama Canal Comm'n, 907 F.2d 532, 534 (5th Cir. 1990) ("The mandamus statute . . . waives, for some purposes, the sovereign immunity of the United States.") (quotations and citations omitted). [*16] n39 Washington Legal Found., 89 F.3d at 901. n40 Larson v. Domestic & Foreign Commerce Corp., 337 U.S. 682, 689, 93 L. Ed. 1628, 69 S. Ct. 1457 (1949); see also Dugan v. Rank, 372 U.S. 609, 621-22, 10 L. Ed. 2d 15, 83 S. Ct. 999 (1963).- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

1. Patent Reexamination Any person may file a request for reexamination, either on an ex parte or inter partes basis. n41 Section 302, which provides for ex parte reexamination, states in relevant part:Any person at any time may file a request for reexamination by the [PTO] of any claim of a patent on the basis of any prior art cited under the provisions of section 301 of this title. n42 The request must be in writing and must be accompanied by payment of a reexamination fee established by the Director pursuant to the provisions of section 41 . . . . n43 Alternatively, section 311 governs inter partes reexamination and reads, in relevant part: (a) Any third-party requester at any time may file a request for inter partes reexamination by the [PTO] of a patent on the basis of any prior [*17] art cited under the provisions of section 301.(b) The request shall-(1) be in writing, include the identity of the real party in interest, and be accompanied by payment of an inter partes reexamination fee established by the Director under section 41; and (2) set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested. n44 Either in response to an application for reexamination or on his own initiative, the Director of the PTO is responsible for "determining whether a substantial new question of patentability affecting any

claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications." n45 If the Director of the PTO finds that a substantial new question of patentability exists, reexamination proceedings are conducted pursuant to section 305, and may thereafter be appealed in accordance with sections 141 and 145. n46 For instance, "a . . . third-party requester in an inter partes reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision in an appeal to the Board of Patent Appeals and Interferences . . . may [*18] appeal the decision." n47 - Footnotes - - - - - - - - - - - - - - - - n41 See 35 U.S.C. §§ 302, 311. 42 Section 301 permits "any person at any time" to write to the PTO to cite "prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent." 35 U.S.C. § 301.n43 35 U.S.C. § 302; see also 37 C.F.R. § 1.510 (listing requirements to apply for ex parte reexamination). n44 35 U.S.C. § 311; see also 37 C.F.R. § 1.913 (discussing process for filing a request for inter partes reexamination). n45 35 U.S.C. § 303(a); see also 37 C.F.R. § 1.520 ("The Director, at any time during the period

of enforceability of a patent, may determine whether or not a substantial new question of patentability is raised by patents . . . which have been discovered by the Director or [] have been brought to the Director's attention, even though no request for reexamination has been filed . . . . The Director may initiate ex parte reexamination without a request for reexamination . . . ."). [*19] n46 See 35 U.S.C. § 305. n47 35 U.S.C. § 141 (permitting appeal of reexamination decisions "only to the [Federal Circuit]"); see also 35 U.S.C. § 315(b) (describing appeals process for a third-party requestor).- - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - -

2. Reexamination of BLAs The FDA's regulation of biological products is governed by the Public Health Service Act ("PHSA"), n48 pursuant to which the distribution of biological products is prohibited unless "a biologics license is in effect for the biological product" and certain other labeling and handling conditions are met. n49 Pursuant to the PHSA, the Secretary of Health and Human Services must establish regulations for the approval, suspension, and revocation of biologics licenses. n50

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n48 42 U.S.C. § 201 et seq.n49 42 U.S.C. § 262(a)(1)(A). "Biological product" refers to "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(h)(3)(i). [*20] n50 42 U.S.C. § 262(a)(3) ("The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).").- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - The Commissioner of Food and Drugs has the authority to promulgate regulations for the approval, suspension, and revocation of biologics licenses. Under these regulations, to qualify for such a license, a manufacturer must "submit an application to the Director, Center for Biologics Evaluation and Research ("CBER") . . . [as well as] data derived from nonclinical laboratory and clinical studies [] demonstrating that the manufactured product meets prescribed requirements of safety, purity, and potency." n51 The Director for the CBER or the Commissioner of Food and

Drugs may refuse a license pursuant to the following regulation, which states, in relevant part: (a) A biologics license shall be issued upon a determination by the Director, [CBER] that the establishment(s) and the product meet the applicable requirements established in this chapter. A biologics license shall be [*21] valid until suspended or revoked. (b) If the Commissioner determines that the establishment or product does not meet the requirements established in this chapter, the biologics license application shall be denied and the applicant shall be informed of the grounds for, and of an opportunity for a hearing on, the decision. n52- - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -n51 21 C.F.R. § 601.2(a). n52 21 CFR § 601.4. - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

D. RICO Claims RICO provides for a private cause of action where a person has been "injured in his business or property by reason of a violation of section 1962." n53 To establish a civil RICO claim pursuant to 18 U.S.C. § 1964(c), a plaintiff must prove an injury resulting from "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." n54 - - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -

n53 18 U.S.C. § 1964(c). n54 Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 491, 87 L. Ed. 2d 346, 105 S. Ct. 3275 (1985).- - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

[*22] "Although the language of the RICO statute is broad, courts have held that the United States is not considered a 'person' under RICO and therefore, as a matter of law, is not a proper party to a RICO claim." n55 The Second Circuit has explained: Under RICO, a "person" can sue or be sued, and the statute does not distinguish between the definition of a potential plaintiff and defendant. The disadvantage of being a "person" within the meaning of RICO is that it subjects qualifying entities to the powerful and expansive criminal and civil liability provisions of the Act. Whether the government has standing to sue and whether it has waived its sovereign immunity may, in the abstract, be different questions, but in this case the answer to one is apparently the answer to both. n56 "Along these lines, other courts have rejected RICO claims brought against the United States as a defendant, holding that the statute does not contain the requisite express and unequivocal waiver of the United States' sovereign immunity." n57 Moreover, "some courts have stated that, while the legislative history of RICO may

indicate an intention by Congress to render local governmental entities [*23] liable, it cannot be read to suggest that the United States or federal agencies should be liable." n58 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -n55 Spinale v. United States, 2004 U.S. Dist. LEXIS 238, No. 03 Civ.1704, 2004 WL 50873, at *7 (S.D.N.Y. Jan. 9, 2004) (dismissing RICO claims against federal agents on sovereign immunity grounds). n56 United States v. Bonanno Organized Crime Family of La Cosa Nostra, 879 F.2d 20, 22-23 (2d Cir. 1989). n57 Spinale, 2004 U.S. Dist. LEXIS 238, 2004 WL 50873, at *7 (citing cases). n58 Id. (citing cases).- - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

III. DISCUSSION A. Sovereign Immunity As an initial matter, the parties' submissions have raised questions about the identity of the proper defendants in this action. n59 Neither the United States nor any federal agency is named as a party defendant. n60 Rather, this action is brought against the Commissioners of the PTO and the FDA. Pieczenik also purports to sue defendants in their "individual capacities." n61 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -n59 See, e.g., Defendants' Reply Memorandum of Law in Further

Support of Their Motion to Dismiss ("Def. Reply") at 2-3 (arguing, that despite plaintiff's objections, the "current action is properly construed as an action against the United States, and is barred by the doctrine of sovereign immunity."). [*24] n60 See generally Compl.n61 Plaintiff's Memorandum of Law in Opposition to Defendants' Motion to Dismiss and in Support of His Cross-Motions ("Pl. Opp.") at 7 ("Whereas Plaintiff has held in Third Amended Complaint that the Commissioner of the [PTO] and the Commissioner of the [FDA] in their individual capacities were proper RICO persons.").- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - -

-The "denomination of the defendant is not dispositive of the question of whether the suit is, in reality, one against the United States." n62 Although Pieczenik purports to sue defendants in their individual capacities, the requested relief is predicated on their authority as Government officials. n63 As such, he is clearly suing defendants in their official capacity. This conclusion is further underscored by the allegations pled in the Complaint, where Pieczenik consistently avers that the complained-of action (or omission) was undertaken (or not undertaken) by the "PTO" and the "FDA." This is essentially a suit against the United States,

and therefore Pieczenik's contention that the defendants "are not 'sovereigns' in-and-for themselves" [*25] and are therefore not entitled to sovereign immunity lacks merit. n64 Moreover, Pieczenik has not identified, nor has a survey of case law revealed, a basis for requiring the United States to move to substitute itself as a party defendant for the federal employees sued herein. n65 Thus, the "cross-motions": (1) for denial of defendants' motion because the U.S. Government has "acted as if it has substituted itself for the [Commissioners of the PTO and FDA]," without filing a motion for substitution or "declaration of representative" n66 and (2) to compel the Government to file a Motion of Substitution are denied. n67

- - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - - -n62 Mendoza Toro v. Gil, 110 F. Supp. 2d 28, 33 (D.P.R. 2000). n63 See Compl. PP 9-10. n64 Pl. Opp. at 2. n65 Where a plaintiff brings a federal tort claim, certification by the Attorney General "that the defendant employee was acting within the scope of his office or employment at the time of the incident out of which the claim arose" is required to substitute the United States as the party defendant. 28 U.S.C.

§ 2679(d)(1). However, Pieczenik's claims do not fall under the Federal Tort Claims Act, and section 2679(d)(1) does not govern. [*26] n66 Pl. Opp. at 2.- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - -

B. Mandamus Relief 1. Patent Reexamination by the PTO Pieczenik requests that this Court compel the Commissioner of the PTO to reexamine "patents in this litigation to be in complete compliance with 35 USC § 290 and/or 15 USC§ 1116 and which falls under 37 CFR 1.501, 37 CFR 1.502[,] 37 CFR 1.525, 37 CFR 1.520, 37 CFR 1.535, 37 CFR 1.510, and 35 USC 102(e)." n68 He argues that even though he did not file for patent reevaluation, he is nonetheless entitled to PTO review of certain patents because the administrative procedures associated with reexamination applications are prohibitively expensive. n69 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - n67 Pl. Sur-Reply at 2. Pieczenik's cross-motion to compel the Government to file an amended reply "explaining the NIH, [] Army and [] Navy's infringement" must also be denied as none of these entities is named as a defendant or is otherwise involved in this litigation. [*27] n68 Compl. P 19. In general, these statutory and regulatory

provisions describe the method for requesting patent reexamination. See, e.g., supra notes 10, 43. n69 Compl. P 41. Pieczenik also argues that "the [PTO] and its regulations and laws do not allow a true inventor to question the validity, in a significant manner, of a patent unless [he] has a patent pending in the [PTO]." Compl P 39. But, this argument fails - any party may request reexamination, irrespective of whether he has a patent pending in the PTO.- - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - -

Pieczenik's allegations fail adequately to demonstrate either that the United States has waived sovereign immunity or that sovereign immunity does not bar his action. He has not identified an applicable statute providing for the waiver of sovereign immunity. n70 Moreover, because Pieczenik has not shown that the Commissioner of the PTO owes him a duty to reexamine the relevant patents absent Pieczenik's submission of an application for patent review, this action does not fall within any exception to sovereign immunity. Pieczenik does not deny that he has not [*28] followed the administrative procedures governing patent reexamination, opting instead to e-mail PTO officials to request that the PTO

commence reexamination proceedings. Although federal regulations permit the Director of the PTO, on his own initiative at any time, to initiate patent reexamination, he is not obligated to do so. n71 Because no official employed by the PTO had a duty to grant Pieczenik's informal request for action, this does not qualify as an exception to sovereign immunity.- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - -n70 I note that the waiver of sovereign immunity contained in section 702 of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 702-06, is inapplicable. "It is not necessary that the suit be brought under the APA for section 702's waiver to apply." Swan v. Clinton, 321 U.S. App. D.C. 359, 100 F.3d 973, 981 n.4 (D.C. Cir. 1996). Accordingly, although not raised by Pieczenik, it is appropriate to consider whether section 702 permits this suit to proceed. Section 702 provides: A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall

not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. 5 U.S.C. § 702. The Complaint, however, fails to satisfy the requirements set forth under the APA, because there has been no final "agency action" for which Pieczenik is seeking review. See id.; 5 U.S.C. § 704. Pieczenik does not allege that he filed an application for ex parte or inter partes reexamination with the Commissioner of the PTO, nor did he request patent review from the Commissioner of the FDA. [*29] n71 See 35 U.S.C. § 303(a); 37 C.F.R. § 1.520- - - - - - - - - - - - End Footnotes- - - - - - - - - - -

Finally, Pieczenik alludes to the PTO's violation of his "Constitutional rights and their own regulations," through its imposition of fees in connection with applications for reexamination. n72 Liberally construed, this could be interpreted as an argument that the Commissioner of the PTO acted pursuant to governmental authority, but in violation of Pieczenik's clearly established constitutional or statutory rights. n73 But this argument fails because the fee schedule is not in contravention of, but based on, statutory authority.

n74 Nor can this financial burden permit the circumvention of the PTO's administrative procedures governing reexamination requests. Courts have found that "ordinary litigation expenses which accompany administrative relief do not excuse plaintiffs from the requirement to exhaust administrative remedies, no matter how substantial and nonrecoverable are the expenses." n75 Accordingly, the Commissioner of the PTO is shielded from this action by the doctrine of sovereign immunity. [*30] n76 - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - -n72 Compl. P 42. n73 See supra note 33 and accompanying text. n74 See 35 U.S.C. § 41. n75 Moncrief v. United States, 43 Fed. Cl. 276, 288 (1999) (citing cases). Moreover, defendants point out that the PTO has the discretion to "refund a portion of the fee if it [determines] that the requesting party [has] not raised a substantial question of patentability." Defendants' Memorandum of Law in Support of Their Motion to Dismiss ("Def. Mem.") at 9 (citing 35 U.S.C. § 303(c)). n76 I need not address the issue of mandamus jurisdiction. I note, however, that even if this action was not precluded by the doctrine of sovereign immunity, Pieczenik does not sufficiently allege the existence of mandamus jurisdiction,

having failed to demonstrate that there is a "plainly defined and peremptory duty to perform the act in question." Morelli, 920 F. Supp. at 558. Reexamination by the Director of the PTO "on his own initiative" is obviously discretionary. Because a PTO official may not be compelled to perform a discretionary act, there is no basis for asserting mandamus jurisdiction over this action. Cf. Marquez-Ramos v. Reno, 69 F.3d 477, 479 (10th Cir. 1995) ("The 'ministerial-discretionary dichotomy which permeates the jurisprudence of mandamus is merely shorthand for the well-taken rule that to the extent a statute vests discretion in a public official, his exercise of discretion should not be controlled by the judiciary. Thus, the question of whether a particular act is discretionary or ministerial rises to the jurisdictional level.").

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2. Patent Reexamination by the FDA Pieczenik argues that this Court should compel the FDA to conduct a "re examination of Erbitux's [BLA] with regard to all unexpired patents and published patent applications listed in their

FDA's [Form] 356h in light of the published '973 patent application." n77 However, Pieczenik again fails to identify either (1) an applicable statutory waiver of sovereign immunity or (2) any duty on the part of the FDA to reexamine Erbitux's BLA in light of the '973 patent application that brings this action within an exception to sovereign immunity. n78- - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - n77 Compl. P 20. n78 Pieczenik also makes vague references to "direct infringement [of his patents] by the FDA by its purchases of NEB libraries." Pl. Sur-Reply at 2. Although the United States has consented to be sued for its taking of a patent license, see, e.g., Zoltek Corp. v. United States, 58 Fed. Cl. 688, 696 (2003), such a lawsuit must be brought in the U.S. Court of Federal Claims. See 28 U.S.C. § 1498. As such, Pieczenik's claims for patent infringement by the United States, if any, are not properly before this Court.- - - - - - - - - - End Footnotes- - - - - - - - - - - - - - [*32]

Pieczenik asserts that line 13 of FDA Form 356h imposes a duty upon the Commissioner of the FDA to order and conduct patent reexamination. Line 13 states: "This application contains the following items: (Check all that

apply) Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))." n79 As defendants point out, this form is "an application to market a new drug, biologic, or an antibiotic drug for human use Throughout this form, FDA indicates the particular regulation or statue applicable to the information required." n80 Section 355 is a part of the Federal Food, Drug, and Cosmetic Act, which requires an applicant to obtain pre-market approval of a drug by filing a New Drug Application ("NDA"), indicating that line 13 relates to NDAs, not BLAs. n81 Thus, line 13 does not create an obligation for the FDA to review patents. As such, the action against the Commissioner of the FDA must be dismissed on sovereign immunity grounds. n82 - - - - - - - - - - - - - - Footnotes - - - - - - - - - - - - - - - n79 FDA Form 356h n80 Def. Mem. at 7 n.4. n81 See 21 U.S.C. § 355 (describing method for new drug approval). [*33]

n82 For the same reasons set forth in the preceding discussion, this Court also lacks mandamus jurisdiction over the FDA. See supra note 76

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C. RICO Claims Pieczenik argues that defendants have engaged in a number of conspiracies for which they are liable under RICO, but he fails to demonstrate that this Court has jurisdiction over this claim. Because he is suing the Commissioners in their official capacities, he is essentially asserting a RICO claim against the United States. n83 But, RICO does not define a "person" to include the United States, and as such the statute does not amount to a clear, unequivocal waiver of sovereign immunity. n84 Accordingly, the RICO claims against defendants must be dismissed.- - - - - - - - - - - Footnotes - - - - - - - - - - - - - - - n83 Moreover, Pieczenik does not allege facts sufficient for a Bivens claim. As defendants note, "nowhere in the complaint does plaintiff allege a constitutional claim for damages" based on their conduct. Def. Reply at 3. n84 See Spinale, 2004 U.S. Dist. LEXIS 238, 2004 WL 50873, at *7. - - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - [*34]

IV. CONCLUSION For the foregoing reasons, defendants' motion to dismiss for lack of subject-matter jurisdiction is

granted and Pieczenik's cross-motions are denied in their entirety. The Clerk of the Court is directed to close these motions [numbers 85 and 88 on the docket sheet] and this case. SO ORDERED: Shira A. Scheindlin U.S.D.J. Dated: New York, New York May 14, 2004